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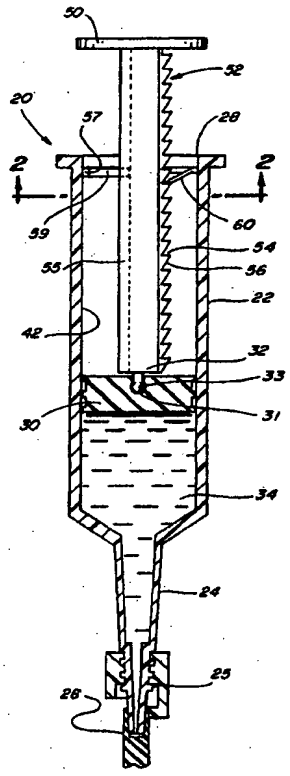
(57) Abstract

A delivery apparatus (20) in the form of a syringe assembly with a piston (30) and including a mechanism for preventing withdrawal of the piston (52, 60). The syringe (20) is preferably pre-filled and sterilized to provide a sterile syringe assembly with sterile contents. By preventing withdrawal of the piston (30), contact of the sterile contents with the exposed portion of the syringe barrel behind the piston and the consequent risk of contamination arising therefrom are avoided.



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MECHANISM PREVENTING REARWARD MOVEMENT OF PISTON SYRINGE

Field of the Invention

The present invention relates generally to delivery apparatus such as syringe assemblies that include a container portion in which a piston or plunger is slidably movable to expel fluid material disposed in the container portion. Specifically, the invention relates to such syringes in which the movement of the piston is restricted or limited.

Description of the Prior Art

Delivery apparatus in the form of syringes having a barrel portion with a delivery or nozzle end and an opposite open end that receives a piston or plunger are known in the prior art. In such devices, the piston is slidable in sealing engagement within the interior surface of the barrel and is movable in a forward direction towards the delivery end for expelling the syringe contents. The piston can also be withdrawn, i.e. moved in a reverse direction away from the delivery end, to perform various tasks, e.g. aspirating fluids which are to be disposed of or aspirating fluids into the syringe barrel for subsequent injection into a living subject, a catheter, etc.

It is further known in the art to manufacture prefilled, sterile delivery apparatus in the form of syringes that have been filled with a medical fluid, sealed to enclose the fluid within a storage volume formed by the syringe barrel, and sterilized to provide sterile

syringe assemblies with sterile contents. For a disclosure of such prefilled syringes, see e.g. U.S. Patent Nos. 4,628,969 and 4,718,463. Prefilled, sterile syringes of the type disclosed in the referenced patents are provided to hospitals or the like in a filled, sealed and sterile condition. To use the syringes, it is only necessary to break the seal of the delivery tip or nozzle, engage the piston with appropriate driving means and dispense the sterile fluid.

In using syringes of the above-described prefilled, sterile type, the interior of the syringe barrel which forms the storage volume and the fluid contents therein are sterile, but the exterior of the syringe, including the portion of the interior of the barrel disposed behind the piston, is usually not sterile. It is thus important that the piston not be withdrawn or retracted since such withdrawal allows contact between the sterile contents in the storage volume and the non-sterile area disposed behind the piston prior to such withdrawal, thus contaminating the sterile contents. As the piston is moved toward the delivery end of the barrel, an increasing area of this interior portion of the barrel behind the piston is exposed to non-sterile ambient conditions. Consequently, any withdrawal of the piston away from the delivery end of the barrel prior to fully expelling the barrel contents creates a significant contamination risk. This risk is caused by the sterile storage volume of the barrel having sterile contents therein communicating with the area of the barrel behind the piston that has been rendered non-sterile by the previous forward expelling movement of the piston. Accordingly, it is an object of the present invention to provide a delivery apparatus in which the aforementioned problems are overcome.

Summary of the Invention

The present invention provides a delivery apparatus in the form of a prefilled, sterile syringe including a container portion with a piston configured to slidably engage the interior surface of the container portion in a sealing fashion, the container portion and the piston being provided with means for preventing withdrawal of the piston away from the delivery end of the container to maintain the sterility of the fluid contents disposed within the container portion.

Brief Description of the Drawings

Other features of the present invention will be apparent from the following description of the preferred embodiments taken in conjunction with the accompanying drawings wherein:

FIG. 1 is a sectional view of a delivery apparatus according to a first embodiment of the present invention;

FIG. 2 is a sectional view taken along line 2-2 of the embodiment shown in FIG. 1;

FIG. 3 is a sectional view of a second embodiment of the present invention;

FIG. 4 is a sectional view taken along lines 4-4 of the embodiment shown in FIG. 3;

FIG. 5 is a sectional view of a third embodiment of the present invention;

FIG. 6 is a sectional view taken along line 6-6 of the embodiment shown in FIG. 5;

FIG. 7 is a plan view of an insert and detent of the embodiment shown in FIGS. 5-6;

FIG. 8 is a sectional view of a fifth embodiment of the present invention;

FIG. 9 is a sectional view taken along lines 9-9 of the embodiment shown in FIG. 8;

FIG. 10 is a sectional view of an insert member used in the embodiment of FIGS. 8-9;

FIG. 11 is a sectional view of a sixth embodiment of the present invention;

FIG. 12 is a sectional view taken along lines 12-12 of the embodiment shown in FIG. 11;

FIG. 13 is a sectional view of a seventh embodiment of the present invention;

FIG. 14 is a side elevation view of a piston and backer plate according to the embodiment shown in FIG. 13;

FIG. 15 is a sectional view of an eighth embodiment of the present invention; and

FIG. 16 is a side elevation view of an adapter according to the embodiment of FIG. 15.

Detailed Description of the Preferred Embodiments

Referring to the embodiment of the present invention shown in Figs. 1 and 2, a delivery apparatus indicated generally at 20 is in the form of a syringe assembly including a housing portion or barrel 22 having a delivery end 24 and an open opposite end 28. A piston 30 is slidably engaged with the interior surface of housing portion 22 and together with the delivery end 24, which is sealed by a tip seal 26, forms a storage volume for the fluid contents 34. As used herein, fluid means a gas, liquid, or combinations thereof. In a preferred embodiment, the fluid is a medical fluid in that it contains a pharmaceutical media, e.g., contrast media. While the housing portion 22 is depicted as being cylindrical, it is to be understood by those skilled in the art that such shape is exemplary and the use of "housing portion" or "barrel" herein encompasses both cylindrical and non-cylindrical syringe container portions, for example, but not limited to, square or triangular containers. The aforementioned storage volume is thus sealed at one end by the tip seal 26 and at the other end by the piston 30. The delivery end 24 is optionally designed to facilitate connection to additional

medical apparatus and can include means, such as but not limited to the thread means 25 shown in Fig. 1, for the attachment of a luer connector of a conventional catheter (not shown). The syringe assembly also includes a push rod 32 for driving the piston 30, as will be discussed below.

In a preferred embodiment of the present invention, the syringe assembly 20 is a prefilled, sterile delivery apparatus which has been presterilized to provide a sterile syringe with sterile contents. Such prefilled, sterile syringes are similar to those disclosed in U.S. Patent Nos. 4,628,969 and 4,718,463, assigned to the same assignee as the present application, the subject matter of which patents is incorporated herein by reference. These prefilled, sterile syringes are assembled, filled, sealed and sterilized to provide a sterile delivery device with sterile contents that can be shipped to hospitals and the like where they can be easily used to inject the contents during medical diagnostic and/or treatment procedures. It is desirable to provide such prefilled syringes in various sizes or volumes, i.e. different amounts of the fluid contents contained therein. It is also desirable to utilize a standard size syringe housing portion which can be filled to different levels to provide the aforementioned different volumes of fluid, as opposed to keeping many different size syringe housing portions on hand at the manufacturing site.

As a result, these prefilled, sterile syringes are often provided for end use in a partially filled condition, i.e. with the piston 30 disposed in the housing portion 22 so as to be displaced from the open end 28, as shown in Fig. 1. As stated above, while the fluid contents 34 contained within housing portion 22 between the piston 30 and the sealed delivery end 24 are sterile, the portion 42 of the interior of the housing 22 disposed behind the piston 30 will generally not be sterile. It is

thus important that the sterile contents 34 not communicate with the aforementioned non-sterile portion 42 of housing portion 22. In many cases, it is desirable to prevent reverse movement of the piston, even initial withdrawal of the piston to aspirate the syringe.

Referring to the embodiment of Figs. 1-2, the push rod 32 is provided with a thumb plate 50 and a series of ratchet-like teeth or projections 52 extending outward from a portion of the push rod 32. As mentioned above with respect to syringe housing portion 22, the push rod 32 is shown as cylindrical in cross-section, but it is to be understood that such shape is exemplary and that push rod 32 can be of a different shape. After placement of the piston within the barrel, the interior surface of housing portion 22 is provided with an insert member 57. The insert member 57 is shaped to fit in open end 28 of housing portion 22 and to be secured thereto by any suitable means as discussed below. A semi-flexible pawl or detent member 60 is carried by insert member 57 and is angled downward (toward the piston 30) from the insert member 57. The detent 60 is configured to engage the ratchet teeth 52 and is deflectable downward but its movement upward is restricted to a predetermined limit, as will be discussed below. The detent 60 is biased by appropriate means to extend to this limit and into engagement with the ratchet teeth 52. In a preferred embodiment, spring biasing means are employed, or alternatively, the detent 60 can be in the form of a leaf spring which can be deflected downward but not upward.

The insert member 57 also includes alignment means in the form of an alignment member 59 configured for engaging alignment means formed in push rod 32 as will be described below. Although the insert member 57 and detent 60 are shown disposed on the interior of housing portion 22 adjacent open end 28, those skilled in the art will recognize that such location is exemplary and that

placement of insert member 57 and detent 60 elsewhere is within the scope of the present invention. After the piston 30 has been placed in housing portion 22, the insert member 57 is positioned therein near the open end 28 thereof. Any suitable means can be used for securing insert member 57 to housing portion 22, including but not limited to adhesive, a press or snap-fit, or a threaded attachment. The push rod 32 is then inserted into housing portion 22 through open end 28 with the ratchet teeth 52 engaging the detent 60 as the push rod 32 moves downward. The push rod 32 includes alignment means in the form of a groove 55 in which the alignment member 59 of insert member 57 is placed as push rod 32 is inserted into housing portion 22. The cooperation of alignment member 59 with groove 55 insures that detent 60 engages ratchet teeth 52 to prevent piston withdrawal as will be discussed below. In the embodiment of Fig. 1, push rod 32 is inserted into housing portion 22 and is attached to piston 30 by a snap-fit. Specifically, the end of push rod 32 opposite finger plate 50 has a protrusion in the form of a knob 33 which is pressed into engagement with a recess 31 formed in piston 30. Engagement between the knob 33 and recess 31 can be accomplished without sufficient force to cause piston 30 to move forward while said engagement is being performed.

The ratchet teeth 52 each include a flat horizontal land surface 54 from which a slanted ramp surface 56 extends downward. The surfaces 54 and 56 engage the detent 60 in a known manner to allow movement of the push rod 32 in the aforementioned downward direction, but to prevent movement in the other direction. Downward movement of the piston 30 and push rod 32 into housing portion 22 is facilitated by placing alignment member 59 in groove 55 and depressing push rod 32. The alignment means insures that the detent 60 engages teeth 52. During downward movement of the push rod 32 towards delivery end

24, detent 60 rides up the slanted surface 56, but upon withdrawal of the push rod 32, detent 60 engages the flat surface 54 to prevent such withdrawal. Thus, the piston 30 and push rod 32 can be moved toward delivery end 24, but movement in the opposite direction is prevented.

As shown in the embodiment of Figs 1-2, the ratchet teeth 52 are formed on one side of the push rod 32 and engage the detent member 60 which extends from the insert member 57. Optionally, it is possible to form the teeth 52 as a plurality of spaced projections extending about the push rod. Further, the use of a non-circular push rod is also encompassed by the present invention, with the ratchet teeth or projections extending from a surface or surfaces thereof. The insert member 57 is positioned in the open end 28 of the syringe barrel 22 after the placement of piston 30, and preferably after the syringe has been subjected to a sterilization procedure, e.g. autoclaving, in which case the prefilled, sterile syringe assembly can be provided for end use with or without push rod 32 secured to piston 30. In the latter case, connection of push rod 32 to piston 30 would be performed by attending medical personnel. However, it is possible to assemble the push rod 32 in the housing portion 22 with the push rod 32 secured to piston 30 before sterilization since the semi-flexible detent 60, which is in engagement with the teeth 52, will permit limited upward movement of the piston 30 and push rod 32 to accommodate expansion of fluid 34 and/or piston 30 during the aforementioned autoclaving. In this case the prefilled, sterile syringe assembly would be provided for end use with the push rod 32 secured to piston 30.

A second embodiment of the present invention is shown in Figs. 3-4 and includes a modified insert member 57a and a modified push rod 32a. The insert member 57a of this embodiment has extending therefrom a semi-flexible detent member 60a but does not have an alignment member because

no alignment means are required with this embodiment. The push rod 32a has a series of coaxial ratchet teeth 52a formed along the length thereof, the teeth 52a extending completely around the push rod 32a as shown in Fig. 4. Because the teeth 52a extend all the way around push rod 32a, the detent 60a will engage the teeth 52a upon insertion of push rod 32a into housing portion 22 regardless of the relative angular positions of the push rod 32a and detent 60a. Rotation of push rod 32a to align the teeth 52a with the detent 60a is not required. Upon insertion of push rod 32a into housing portion 22, the one-way engagement between detent 60a and teeth 52a is like that of the first embodiment. Engagement of push rod 32a with piston 30a can be accomplished as in the first embodiment, or alternatively, can be facilitated by other means including but not limited to rotating a threaded extension of push rod 32a into a threaded recess formed in piston 30a. Rotation of push rod 32a while teeth 52a are engaged by detent 60a is possible to allow such engagement.

As with the first embodiment, the insert member 57a is positioned by suitable means in the open end 28 of the housing portion 22 after placement of piston 30a, and preferably after the syringe has been subjected to a sterilization procedure, e.g. autoclaving, although again it is possible to assemble the push rod 32a to the piston 30a before sterilization due to the semi-flexible nature of detent 60a which allows piston movement due to expansion during autoclaving. The prefilled, sterile syringe of the present invention thus has means for preventing withdrawal of the piston 30a, which withdrawal would lead to the aforementioned contamination risks arising from contact of the sterile fluid 34 with the portion 42 of the interior of housing portion 22.

A third embodiment of the present invention is shown in Figs. 5-7 and includes a further modified insert member

57b with a detent member 60b. The push rod in this embodiment is shown to have teeth 52b similar to the teeth 52 of the first embodiment. The insert member 57b has a semi-flexible detent member 60b which projects inward from an inner edge of member 57b. As seen in Fig. 7, detent member 60b is in the form of a continuous flat member extending downward from insert member 57 (toward piston 30b) with a central aperture 61 through which push rod 32b can be moved downward but not upward. It will be recognized that this shape of the detent 60b is exemplary and that detent 60b can be shaped otherwise so long as push rod 32b will engage said detent 60b at various angular positions of push rod 32b. The operation of the detent 60b and teeth 52b to prevent reverse movement of piston 30b is similar to that of the above embodiments. The push rod 32b can be connected to piston 30b by any suitable means, e.g. the snap-fit or threaded fit of the first two embodiments. The insert member 57b is positioned in housing portion 22 by suitable means discussed above with reference to the first two embodiments. The detent 60b is semi-flexible to allow limited movement of piston 30b during autoclaving, thus permitting attachment of push rod 32b to piston 30b prior to autoclaving as discussed above.

Another embodiment of the present invention (not shown) includes a housing portion 22 having secured thereto the insert member 57b of the embodiment of Figs. 5-7 combined with the push rod 32a of the embodiment of Figs. 3-4. The ratchet teeth 52a extend completely around push rod 32a as discussed above, and the insert member 57b has detent 60b in the form of a continuous member which surrounds push rod 32a upon insertion of the push rod into the housing portion 22. A benefit of this embodiment is that engagement between the detent 60b of insert member 57b and the teeth 52a of push rod 32a occurs completely

around the push rod 32a, providing an enhanced engagement to further prevent reverse movement of the piston.

A fifth embodiment of the present invention shown in Figs. 8-9 includes a syringe with a housing portion 122 having an open end 128 and a delivery end 24, with the delivery end 24 including a sleeve or shroud 40 to facilitate attachment to additional medical apparatus (not shown), e.g. the luer connector of a conventional catheter. The housing portion 122 has provided on its upper interior surface a series of annular ratchet-like teeth 152. Each one of the ratchet teeth includes a horizontal land surface 154 from which a slanted ramp surface 156 extends upward. The ratchet teeth may, as shown in Fig. 10, alternatively be carried by an insert 200 configured and shaped to fit within the housing portion 222, or the housing portion of other embodiments. Insert 200 can be secured within housing portion 222 by any suitable means including but not limited to adhesive or a tight friction fit. The push rod 132 has a thumb plate 150 at an upper end and at its lower end is connected to piston 130 by any suitable means, e.g. the snap-fit or threaded fit of the previously described embodiments. A collar-like member 158 is secured to the push rod 132 adjacent the upper end below thumb plate 150, and a pair of pawl-like detents 160 are secured to and extend from the collar member 158. Those skilled in the art will recognize that it is within the scope of the present invention to utilize other than two detents, e.g. one, three, or more detents. It is likewise within the scope of the present invention to position the collar member 158 on the push rod 132 other than as shown or, alternatively, to secure the detents 160 directly to the push rod, 132 or, as a further alternative, to form the detents 160 integrally with the push rod 132.

The detents 160 engage the ratchet teeth 152 so as to allow downward movement of the push rod 132, but to

prevent movement thereof in an opposite direction in a manner similar to that described with respect to the embodiment of Fig. 1. The detents 160 are biased, preferably spring biased, into engagement with the ratchet teeth 152. As in the case of the embodiments of Figs. 1-4, the syringe 120 is partially filled with sterile fluid 34, and assembly of the push rod 132 with the piston 30 is preferably performed prior to the sterilization procedure, although as in the embodiments of Figs 1-7 the detent 160 is semi-flexible to allow assembly of the push rod 132 to piston 30 before sterilization as discussed above. The combination of the ratchet teeth 152 provided on the interior of the barrel wall and the detents 160 carried by the push rod 132 prevents withdrawal of the piston 130, which withdrawal will cause the sterile fluid 34 to come into contact with the portion 142 of the interior of the housing portion 122 and present a significant contamination risk.

A sixth embodiment of the present invention is shown in Figs. 11-12 in the form of a syringe including a housing portion 122a and a piston 130a with a push rod 132a attached to the piston 130a by any suitable means as discussed above with reference to the above embodiments. The interior of housing portion 122a is provided with a series of ratchet teeth 152a which, as described above regarding Fig. 10, can be provided on a separate insert such as member 200. The ratchet teeth 152a do not cover the entire interior surface of housing portion 122a as they do in the embodiment of Figs. 8-9. The push rod 132a has a detent member 160a secured thereto for engaging the ratchet teeth 152a to prevent reverse movement of push rod 132a and piston 130a. The detent 160a is in the form of a continuous flat member extending away from push rod 132a and will engage ratchet teeth 152a of housing portion 122a as described above, i.e. to allow movement of push rod 132a and piston 130a towards the delivery end to expel

fluid 34 but to prevent movement in the opposite direction.

Further embodiments of the present invention include a syringe with the housing portion 122 of Figs. 8-9, which is covered with ratchet teeth, and the push rod 132a having a continuous detent 160a of Figs. 11-12. In addition, it is possible to have an embodiment of the present invention in the form of syringe having the housing portion 122a of Figs. 11-12, which is partially covered with ratchet teeth 152a, and the push rod 132 and detents 160 of Figs. 8-10. In the embodiment of Figs. 11-12, the attachment of push rod 132a to piston 130a, accomplished by suitable means such as the threaded coupling shown, permanently aligns the detent 160a with ratchet teeth 152a.

With reference to FIGS. 13 and 14, a seventh embodiment of the present invention is indicated generally by reference numeral 220 and is in the form of a delivery apparatus in which the piston 230 is configured to be engaged and driven by a power injector 270. The delivery apparatus includes a container portion 222 having a delivery end 224 and an open opposite end 228. A piston 230 is positioned in container portion 322 so as to seal fluid contents 260 therein. The delivery end 224 preferably has means for attaching the delivery apparatus to auxiliary medical apparatus which can be, e.g. a nut 226 for engaging the luer connector of a catheter (not shown).

The piston 230 has attached thereto, and preferably integral therewith, a backer plate 232. Backer plate 232 is shown in FIG. 14 and includes an upper disc 234 and lower disc 236. Lower disc 236 has a stepped extension 237 which is secured to, e.g., by being embedded in and/or adhesively attached to, piston 230. Backer plate 232 has elongated support members 242, 244 extending between upper and lower discs 234, 236 to provide strength and stability

as described below. The backer plate 232 has a stem portion 242 extending from upper disc 234 and a button 243 formed on the end of stem 242. The stem 242 and button 243 are configured to be engaged by power injector 270 as is known in the art and will not be described herein in detail.

The container portion 222 is provided on its interior wall with a series of ratchet teeth or projections 252 similar to those shown in FIG. 8, i.e., annular projections. Optionally, the teeth can be discontinuous as in the embodiment shown in FIG. 11. As stated above, piston 230 has secured thereto backer plate 232 which is configured to be engaged by a power injector 270. As seen in FIG. 13, the upper disc 234 of backer plate 232 is closely adjacent the uppermost ratchet tooth (or teeth) 252 when the delivery apparatus is ready for use. As power injector 270 drives backer plate 270 and piston 230 forward, upper disc 234 ratchets over teeth 252 due to a limited amount of flexibility of the teeth 252, the upper disc 234, or both the teeth and disc.

As in the previous embodiments, the ratchet teeth 252 are shaped so as to prevent withdrawal of the piston once the disc 234 has slid over the uppermost tooth or teeth. In this manner, withdrawal of the piston is prevented as is the contamination risk associated therewith. A sufficient number of ratchet teeth 252 are formed on the container interior or, optionally, the teeth can be formed on an insert which is placed in the container 222 as in FIG. 10, to permit the fluid 260 to be fully expelled without upper disc 234 of backer plate 232 coming disengaged with the teeth. This prevents withdrawal of the piston after the fluid contents have been partially dispensed.

It is possible to form backer plate 232 with an additional intermediate disc 235 located between upper and lower discs 234, 236 as shown in phantom in FIG. 13. The

disc 235 rides over ratchet teeth 252 and provides additional protection against piston withdrawal. Moreover, disc 235 provides added stability to the backer plate as it is driven to ensure even piston movement and to avoid knocking. Those skilled in the art will recognize, of course, that more than one intermediate disc 235 can be utilized on backer plate 232 without departing from the scope of the present invention.

As previously discussed, it is more economical to utilize one size container portion or syringe barrel for different volume delivery apparatus rather than utilizing different size barrels. As a result, a particular size backer plate may not extend to the open end 328 of container portion 322 if the volume of fluid 310 is below a certain level. It is important that backer plate 332, and specifically stem 242 and button 243, extend far enough toward end 228 so that the power injector 270 can engage same to drive piston 230 forward. Thus, if the volume of fluid is below the aforementioned level, the power injector cannot engage the particular backer plate.

FIGS. 15 and 16 show an eighth embodiment of the present invention which includes a container portion 322 with a piston 330 disposed therein to sealingly enclose fluid 360. The volume of fluid 360 is such that backer plate 232 does not extend far enough toward open end 328 to be engaged by power injector 270. An extension adapter indicated generally at 400 is utilized to extend the effective length of backer plate 332. Adapter 400 may be similar to the adapter disclosed in U.S. Patent Nos. 4,636,198 and 4,705,509, which patents are assigned to the same assignee as the present application and are incorporated herein by reference.

As shown in FIGS. 15 and 16, adapter 400 has an upper disc 402 and a lower disc 404 connected by elongated support members which are preferably arranged perpendicular to each other in cross-section. The upper

disc 402 of adapter 400 has extending therefrom a stem 406 and button 407 similar to that formed on the backer plate 232 for engaging power injector 270. The bottom disc 404 has extending therefrom abutments 412 and clips 414 for respectively engaging the upper surface of disc 234, and the button 407 of backer plate 332. Adapter 400 engages backer plate 232 in a secure manner to transfer the driving force from power injector 270 to piston 230.

The upper and lower discs 402, 404 of adapter 400 preferably engage the inside of container 322 to prevent withdrawal of piston 230, and to provide stability as the adapter 400, backer plate 232, and piston 230 are driven forward to expel fluid 360. The adapter 400 is slid inside container 222 and ratcheted over teeth 252 until the clips 414 securely engage button 407 and stem 406 of backer plate 232. The power injector 270 engages button 407 of adapter 400 to drive the piston 230 forward and expel the fluid 460.

It will be readily recognized by those skilled in the art that the embodiment shown in FIG. 15 is but one example of a partially filled container for which the adapter 400 is suitable. The length of adapter 400 can be varied to fit the particular application, i.e., to extend the effective length of the backer plate as is required depending on the specific volume of fluid. For example, FIG. 16 shows an adapter 400a, the length of which is somewhat exaggerated for clarity, that is longer than adapter 400 and, accordingly, is suitable for use in a prefilled delivery device having a smaller volume of fluid than that in FIG. 15. The components designated by "a" of adapter 400a correspond to those in adapter 400.

In all embodiments, the container, piston moving means, and piston movement preventing means are preferably formed by, e.g., injection molding a plastic material such as polypropylene, polyethylene, or any other suitable polymer. The piston can be formed of a suitable rubber or

plastic material which is likewise molded. The medical fluid disposed in the container portion of each embodiment is preferably contrast media, but it will be recognized that other fluids can be used without departing from the scope of the present invention.

It is apparent that the present invention can be utilized to prevent withdrawal of the piston of a delivery apparatus whether the piston is driven by a hand-operated push rod or the like, or by a power driven injector. In addition, those skilled in the art will appreciate that the many embodiments of the present invention provide numerous possible combinations and arrangements to provide a prefilled, sterile delivery device that prevents withdrawal of the piston.

While the present invention and the embodiments presented herein have been set forth and described in detail for the purposes of making a full and complete disclosure of the subject matter thereof, the disclosure herein presented is not intended to be limiting in any way with respect to the true scope of this invention as the same is set forth in the appended claims.

What is claimed is:

1. A prefilled, sterile delivery apparatus comprising:

a container having a sealed delivery end, with a piston positioned in said container so as to be sealingly slidable against an interior surface of said container;

a storage volume formed in said container, said storage volume containing fluid;

means connected to said piston for moving said piston within said container along said interior surface in a forward direction toward said delivery end to expel said fluid contained within said container; and

means for preventing movement of said piston in a reverse direction away from said delivery end;

wherein the entire apparatus is sterilized to provide a sterile delivery apparatus with sterile contents.

2. A delivery apparatus as claimed in claim 1, wherein at least one detent member is carried by an insert member attached to the interior surface of the container which detent engages a series of projections formed on a push rod which is connected to said piston for moving the piston toward said delivery end.

3. A delivery apparatus as claimed in claim 2, including alignment means for aligning said at least one detent member with said series of projections.

4. A delivery apparatus as claimed in claim 1, wherein said means for continuously preventing movement of said piston in the reverse direction away from said delivery end includes at least one detent member carried by said means for moving said piston and a plurality of projections carried by the interior of said container, whereby said detent member and said projections permit movement of said piston toward said delivery end but

prevent movement of said piston away from said delivery end.

5. A delivery apparatus as claimed in claim 4, including alignment means for aligning said at least one detent member with said plurality of projections.

6. A delivery apparatus as claimed in claim 4, wherein said means for moving the piston includes a backer plate configured to be engaged by a power injector.

7. A delivery apparatus as claimed in claim 6, wherein said means for moving the piston includes an adapter which is attachable to said backer plate, said adapter being configured to be engaged by a power injector.

8. A delivery apparatus as claimed in claim 4, wherein said plurality of projections carried by the container are provided on an insert member that fits within the container.

9. A delivery apparatus as claimed in claim 1, wherein said means for moving the piston includes a backer plate configured to be engaged by a power injector.

10. A delivery apparatus as claimed in claim 9, wherein said means for moving the piston includes an adapter which is attachable to said backer plate, said adapter being configured to be engaged by a power injector.

11. A prefilled, sterile delivery apparatus as claimed in claim 1, wherein said means for preventing movement of the piston in the reverse direction permits said piston to move a limited distance in said reverse

direction to allow the filled, sealed delivery apparatus to be sterilized with the push rod connected to the piston.

12. A delivery apparatus as claimed in claim 11, wherein said means for moving the piston includes a backer plate configured to be engaged by a power injector.

13. A delivery apparatus as claimed in claim 12, wherein said means for moving the piston includes an adapter which is attachable to said backer plate, said adapter being configured to be engaged by a power injector.

14. A method of producing a prefilled, sterile delivery apparatus, the method comprising the steps of:

forming a container having a sealed delivery tip and a hollow interior, said container having an open end disposed opposite said sealed delivery tip;

providing the container with means for preventing movement of a piston positioned in the container beyond a limited distance in a direction away from said sealed delivery tip and toward said open opposite end, said means for preventing piston movement cooperating with means for driving the piston toward said delivery tip to prevent movement of the piston in said direction;

filling said container with a predetermined quantity of medical fluid and sealing said open end with a piston to form a sealed container having medical fluid therein; and

sterilizing the filled, sealed container with the piston disposed therein to produce a prefilled, sterile delivery apparatus.

15. A method according to claim 14, wherein said sterilizing step is carried out by autoclaving the filled, sealed container.

16. A method of producing a prefilled, sterile delivery apparatus, the method comprising the steps of:

forming a container having a sealed delivery tip and a hollow interior, said container having an open end disposed opposite said sealed delivery tip;

providing the container with means for preventing movement of a piston positioned in the container in a direction away from said sealed delivery tip and toward said open opposite end, said means for preventing piston movement cooperating with means for driving the piston toward said delivery tip to prevent movement of the piston in said direction;

filling said container with a predetermined quantity of medical fluid and sealing said open end with a piston to form a sealed container having medical fluid therein; and

sterilizing the filled, sealed container with the piston disposed therein to produce a prefilled, sterile delivery apparatus.

17. A method according to claim 16, wherein said sterilizing step is carried out by autoclaving the filled, sealed container.

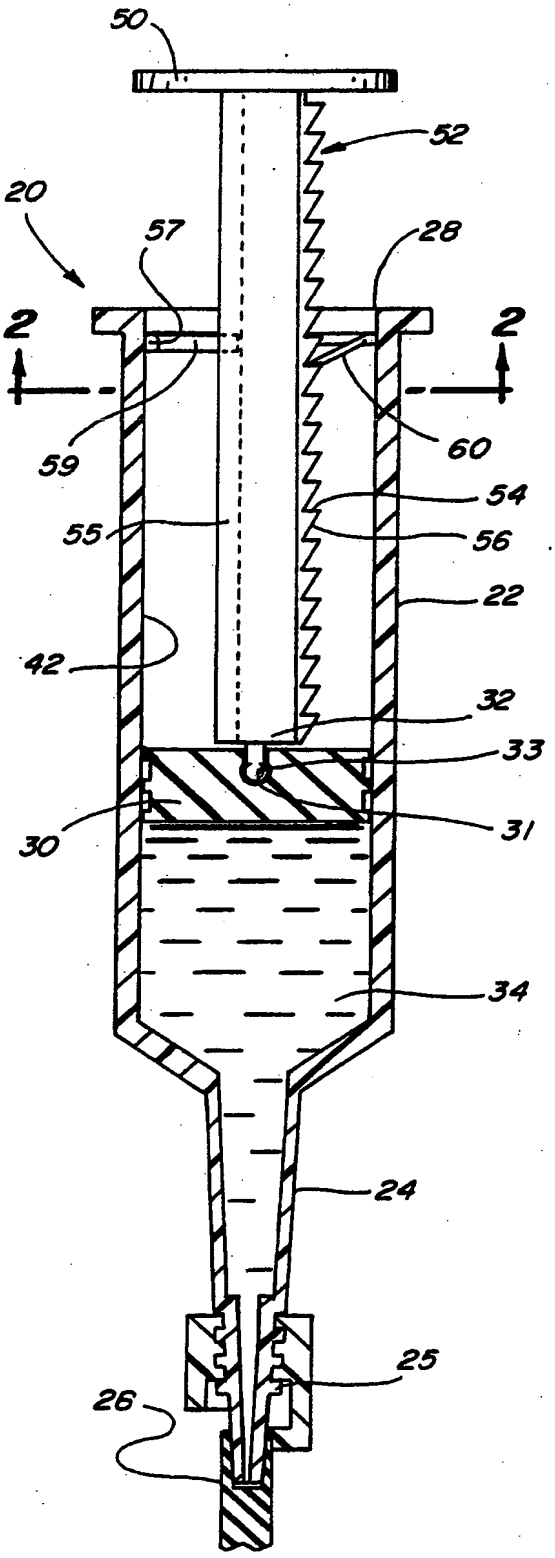


Fig. 1

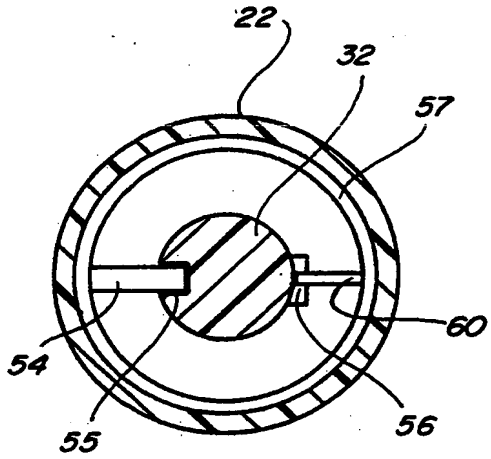


Fig. 2

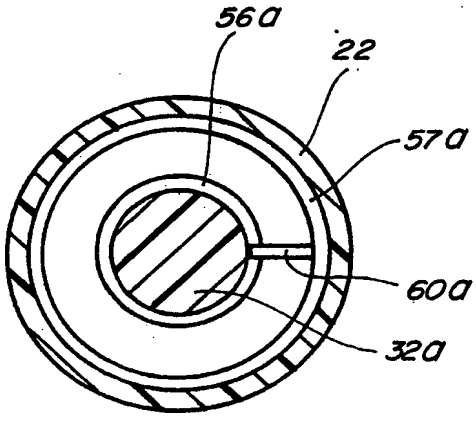
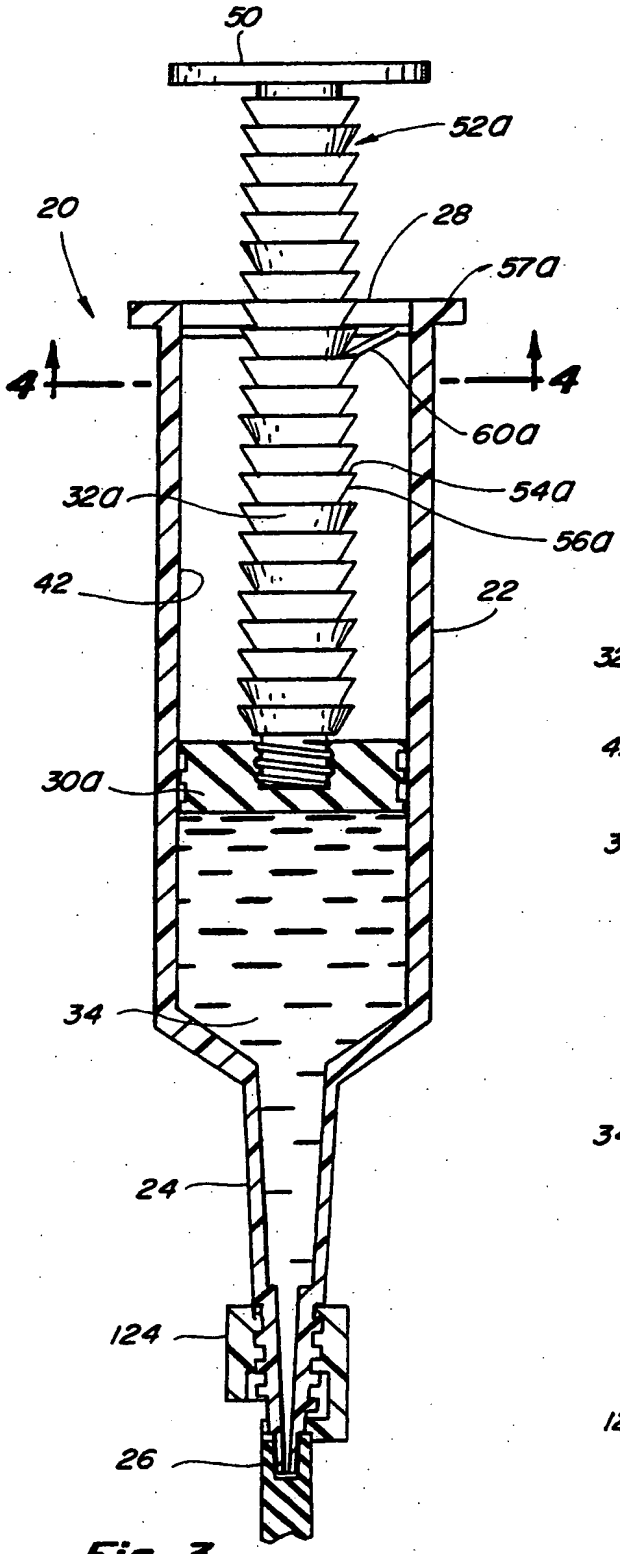


Fig. 4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30a
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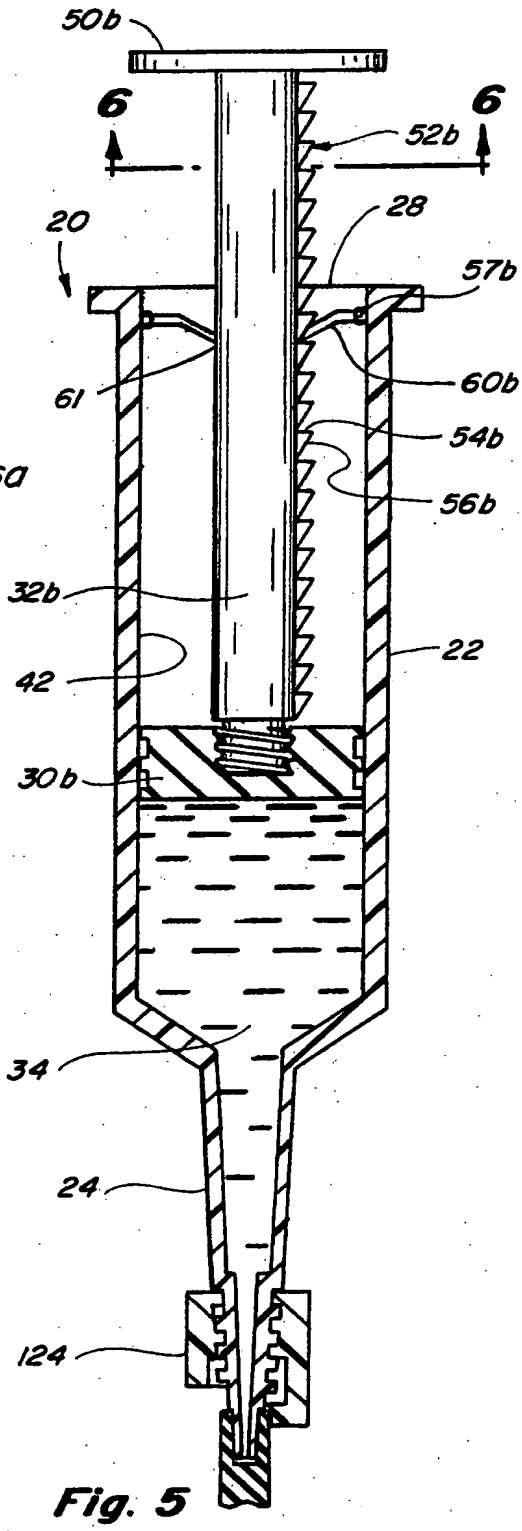
124
26

Fig. 3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124

Fig. 5

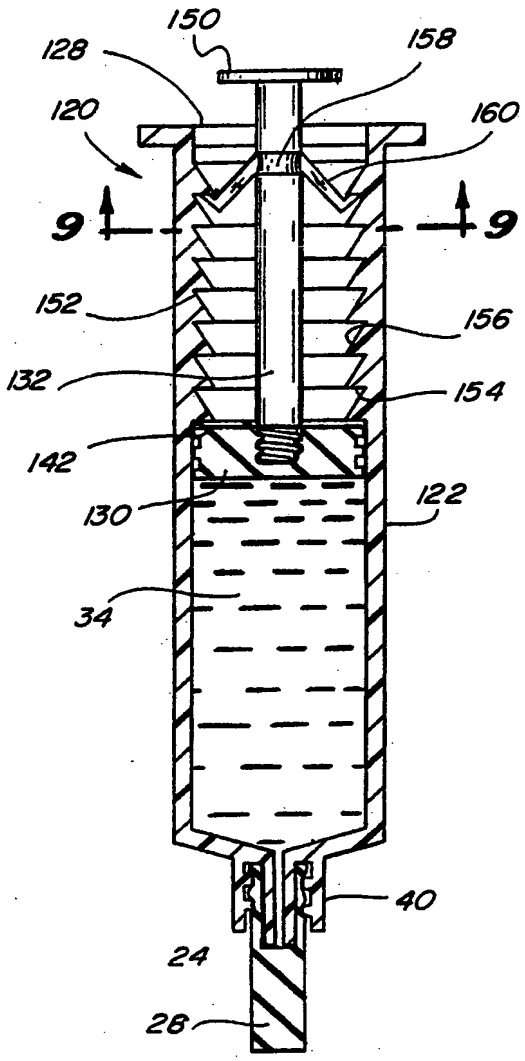

Fig. 8

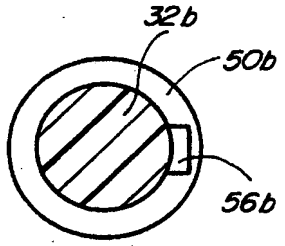

Fig. 6

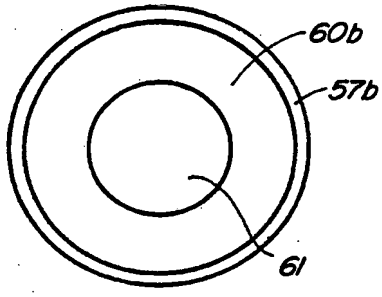

Fig. 7

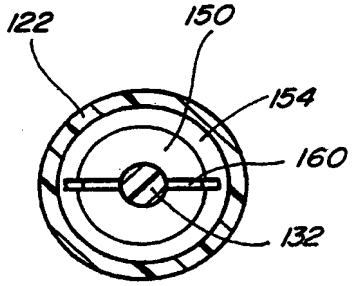

Fig. 9

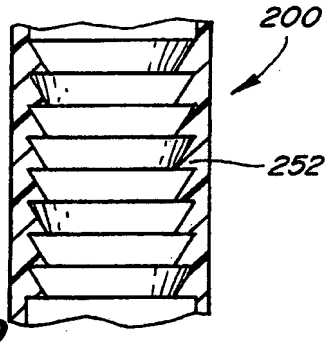

Fig. 10

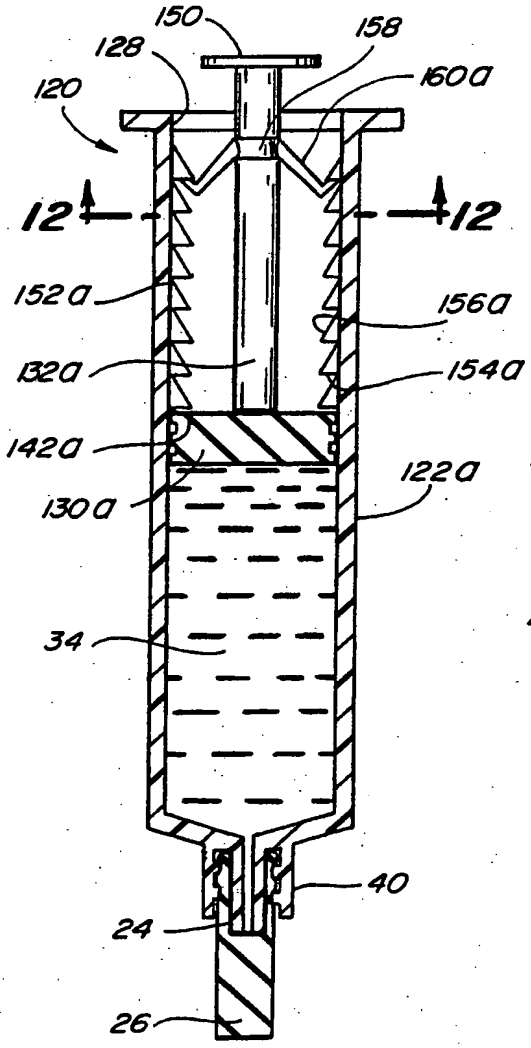

Fig. 11

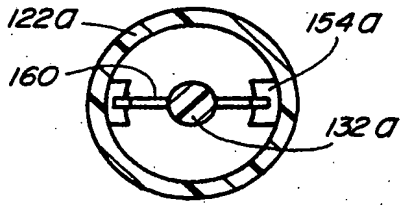

Fig. 12

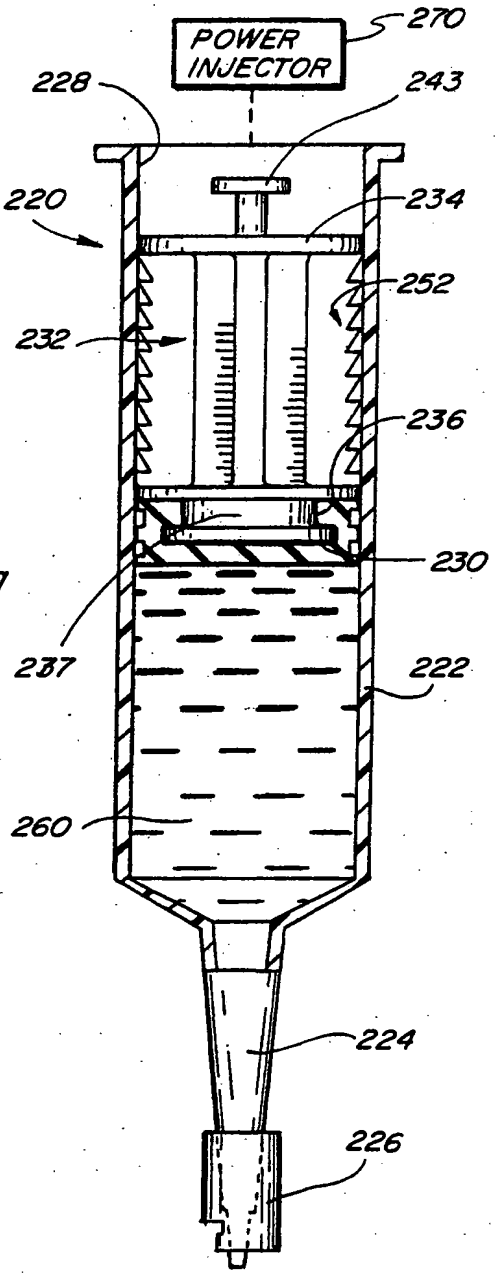

Fig. 13

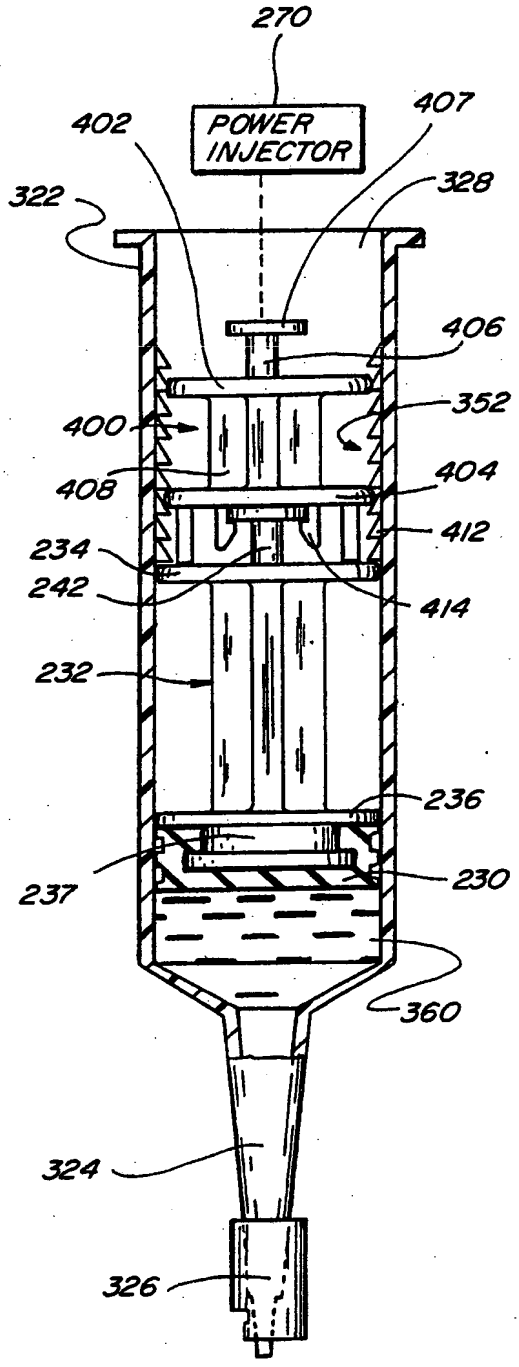

Fig. 15

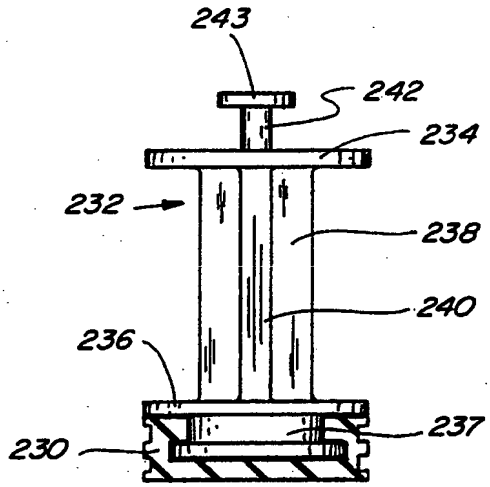

Fig. 14

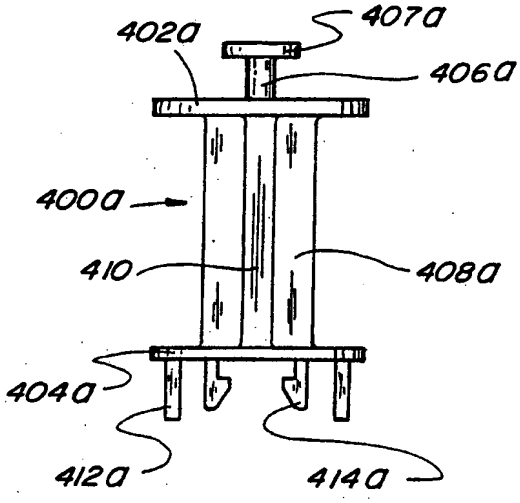

Fig. 16

INTERNATIONAL SEARCH REPORT

Ir. ational application No.
PCT/US93/11978

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61M 5/00, 5/32, 5/315
US CL :604/187, 199, 218, 221, 228
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

- U.S. : 604/110, 187, 218, 232

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 90/11790 (McMahon) 18 OCTOBER 1990, See entire reference.	1-5, 11, 14, 15, 16, 17
X	US, A, 4,957,490 (Byrne et al) 18 September 1990. See entire reference.	7-10, 12, 13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 03 FEBRUARY 1994	Date of mailing of the international search report 30 MAR 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer N. KENT GRING Telephone No. (703) 308-3175

Form PCT/ISA/210 (second sheet)(July 1992)*